ISE S.r.l.
CUSTOMISED SOLUTIONS FOR YOUR LABORATORY

Fibrinogen– Instructions for use

R1: 1x 25 mL
R2: 1x 5 mL

REF A-R1100003301

IVD

CE

SUMMARY AND EXPLANATION OF THE TEST

Minimising blood loss is accomplished by three events. One is a clumping of platelets in the blood at the site of injury.
Another is a vasoconstriction of the injured vessel to reduce the flow through the break.
The third event is aggregation of a protein, fibrin, into a clot – a stable three-dimensional lattice- that is strong enough to seal the damaged vessel while repairs are being made. Clotting occurs because a soluble blood plasma protein, fibrinogen, is partially hydrolysed to form fibrin.
Elevated levels of fibrinogen in plasma are to be expected in inflammatory processes, after major trauma or surgery and also occur with metastasing tumours.
Decreased levels of fibrinogen can occur in consumption coagulopathies, e.g. disseminated intravascular coagulation (DIC), primary hyperfibrinolysis, hepatic insufficiency and genetic deficiency.
Epidemiological studies have shown that elevated plasma levels of fibrinogen are associated with an increased risk of arteriosclerosis.

PRINCIPLE OF THE TEST

Measurement of antigen-antibody reaction by the end-point method.

Fibrinogen Reagent Kit
Code A-R1100003301
Reagent 1 (R1) - Buffer - 1 x 23.5 mL/vial
Reagent 2 (R2) - 1 x 4.5 mL/vial
Each vial is ready to use and contains:

Reagent 1:	**Conc.**	**U.M.**
Phosphate buffered saline (pH 7.43)	/	/
Polyethylene glycol	60	g/L
Sodium azide	0,95	g/L
Reagent 2:	**Conc.**	**U.M.**
Phosphate buffered saline (pH 7.43)	/	/
Polyclonal goat anti-human Fibrinogen (variable)	/	/
Sodium azide	0,95	g/L

Reagent Preparation:
Liquids reagents ready for use.

Storage and Stability:
If stored at 2 - 8°C avoiding direct light, the reactants remain stable until the expiration date printed on the label.
Stability in the instrument is at least 4 weeks if contamination is avoided. Do not freeze.
Do not freeze the reagents.

EQUIPMENT / ACCESSORIES REQUIRED AND NOT SUPPLIED

General laboratory equipment
Saline (9 g/L)
Calibrators and/or Control
(Pooled human serum, liquid and stabilized. Contains 0.95 g/L sodium azide. Value is stated in the insert)

PRECAUTIONS AND LIMITATIONS

For *in vitro* diagnostic use.
Only experienced laboratory personnel should use this test and handling should be in agreement with Good Laboratory Practice (GLP).
Reagents from different lots must not be interchanged.

Safety Precautions

1. Each donor unit used in the preparation of the reagents, standards and controls was found to be negative for the presence of HIV1 and HIV2 antibodies, as well as for the hepatitis B surface antigen and anti-hepatitis C antibodies, using a method approved by the FDA
2. Do not pipet by mouth.
3. Do not smoke, eat or apply cosmetics in areas in which patients' samples or kit reagents are handled.
4. Cuts, abrasions, and other skin lesions should be properly protected with an appropriate waterproof dressing.
5. Take care to avoid self-inoculation, splashing of mucous membranes or generation of aerosols.
6. Laboratory gloves should be worn while handling patients' samples or disposing of solid or liquid wastes.
7. In addition to the eventual risk indications regarding the active components, the reagents contain inactive components such as preservatives (e.g. sodium azide or others) and detergents. The total concentrations of these components is lower than the limits reported by the current directive sand following modification and amendments. However, it is recommended to handle reagents carefully, to avoid ingestion and contact with eyes, skin and mucus membranes and to use laboratory reagents according to good laboratory practice.
8. All human samples must be handled and disposed of as potentially infectious materials.
9. For information about safe handling, read carefully the Material Safety Data Sheet (MSDS).

Disposal of Reagents
Disposal of reagents must be performed in accordance with the EC regulations regarding waste, or the local national or regional legislation.

SPECIMEN COLLECTION AND STORAGE

Use fresh serum.
If the test can not be carried out on the same day, the serum may be stored at 2 - 8°C for 48 hours. If stored for a longer period, the sample should be frozen.

Quality control
It's necessary, each time the kit is used, to perform the quality controls and to check that values obtained are within the acceptance range provided in the insert. Each laboratory should establish its own mean and standard deviation and adopt a quality control program to monitor laboratory testing.

Automation
All applications not explicitly approved by ISE S.r.l. cannot be guaranteed in terms of performance, and must therefore be established by the operator.

Procedure
Manual:
Sample/Control/standard: dilute 1:2 in saline 9 g/L.
Reference curve: generate a reference curve by diluting the Fibrinogen standard
Ref: R-1300002201 1:1, 1:2, 1:4, 1:8, 1:16, in saline 9 g/L. Use saline 9g/L as zero point.

Method for automated instrumentation

Analyzer:	**Miura Family**		
Analyte Name :	**Fibrinogen**	Ref.:	A-R1100003301
Method Code:	**FIB**		
Type:	**Different. Sample Blk.**		
Unit:	**mg/dL**		
Filter F1:	**340 nm**		
Blank in calculation:	**Not Used**		
	Reaction volume		**U.M.**
Sample volume:	**3**		µL
Volume Reagent 1:	**240**		µL
Volume Reagent 2:	**55**		µL
Incubation Time	**60**		Sec.
Reading Time:	**300**		Sec.
Calibration	**See Reference Curve**		

EXPECTED VALUES

200 - 400 mg/dL
Reference values are considered indicative since each laboratory should establish reference ranges for its own patient population. The analytical results should be evaluated with other information coming from patient's clinical history.

PERFORMANCE CHARACTERISTICS

The performance characteristics for the Fibrinogen reagents were measured on a clinical chemistry analyzer.
Measuring Range: 0 - 523 mg/dL
Detection Limit: 4.5 mg/dL
Hookeffect: No risk
Sensitivity: 0.0004802 ABS units/concentration unit

Precision: [%CV]		Low	Medium	High
	Intra-Run	2.20	3.76	3.69
	Inter-Run	3.15	2.56	3.69
Accuracy: [mg/dL]	Control	Assigned	Measured	
	Behring	244 (207 - 281)	265.6	

Specificity: Monospecific
Interferences: No interference for: Haemoglobin (1000 mg/dL), Bilirubin (30 mg/dL), Triglyceride (2500 mg/dL), Natrium Citrate (1000 mg/dL) and EDTA (10 mg/mL).
Limitations: None
Comparison with Nephelometry: y = 0.9904x - 11.196 / r = 0.9842
Stability at 4°C: at least 3 years after production

BIBLIOGRAPHY

1. Ernst, E. und Resch, K. L., Ann. Intern. Med. 118, 956 (1993)
2. Cremer, P. et al., Diagnose & Labor 42, 28 (1992)
3. Dati. F. et al., Klin. Lab 39, 669 (199 3)

Numero lotto / Lot numer


Consultare la metodica operativa / consult instructions for use

Per uso diagnostico in-vitro / For in-vitro diagnostic use


Prodotto da / manufactured by


Data di scadenza / expiry date


Temp. Di Conservazione / storage temperature

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